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Investigating the association of the intention to join an accreditation programme with the maturity of quality management, patient care and debt among hospitals: a cross-sectional study in Hungary

Title page

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ABSTRACT

Objective: Quantitative studies have shown the various benefits for having accreditation in hospitals. However, the question of why hospitals apply for an accreditation has not yet been explored. This study aimed to investigate the possible association between joining an accreditation programme with various hospital characteristics.

Design: A cross-sectional study was implemented using the databases of the 2013 Hungarian hospital survey and of the Hungarian State Treasury.

Setting: Public general hospitals in Hungary.

Participants: The analysis involved 44 public general hospitals, fourteen of which joined the preparatory project for a newly developed accreditation programme.

Main outcome measures: The outcomes included the percentage of compliance in quality management, patient information and identification, internal professional regulation, safe surgery, pressure sore prevention, infection control, the opinions of the heads of quality management regarding the usefulness of quality management and clinical audits, and finally, the total debt of the hospital per bed and per discharged patient.

Results: According to our findings, the general hospitals joining the preparatory project of the accreditation programme performed better in four of the six investigated activities, the head of quality management had a better opinion on the usefulness of quality management, and both the debt per bed number and the debt per discharged patient were lower than those who did not join. However, no statistically significant differences between the two groups were found in any of the examined outcomes.

Conclusions: The findings suggest that hospital characteristics in general do not contribute or inhibit the chance for applying for an accreditation programme. Thus, we recommend that future studies investigating this question should focus on the knowledge, interest, attitudes and beliefs of the hospital management.

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Keywords: Quality in health care, Clinical governance, Organisation of health services, Accreditation

Strengths and limitations of this study

- Due to the high response rate, the findings of this study can be generalized to all public general hospitals in Hungary.

- Since the hospital survey was conducted in a single country, different health policies or financial environments did not impact the findings.

- The findings cannot be generalized to private hospitals.

- The questionnaire used in the study was originally designed for a national survey, not as a research instrument.

INTRODUCTION

The quantitative studies that investigate the usefulness of accreditation in health care are based on the premise that the written regulations in the accreditation standards directly influence the process of care. From studies that address this topic, we know that the accreditation of hospitals is associated with more mature quality management, better clinical practice,[1] safer patient care,[1,2] increased compliance in documentation,[3-5] shorter length of stay for psychiatric inpatients[6] and better attitudes towards medication error reporting[7] but are not associated with better performance measures for acute stroke, heart failure and ulcers.[8] Furthermore, other studies show that this influence goes beyond the process of care and accreditation by also predicting organizational culture and leadership[9] and supporting the promotion of change and professional development.[10] Although accreditation does not affect outcomes directly because of the logical chain of Donabedian's structure-process-outcome,[11] we assume that if a positive association exists between accreditation and the process of care, then this positive effect must also be reflected in various outcomes. Although none of the studies found any association between accreditation and patient satisfaction,[12-15] Danish studies have revealed that patients in fully accredited hospitals had a lower 30-day mortality risk[16] and a modestly shorter length of stay but not a lower chance of acute readmission compared to patients in partially accredited hospitals,[17] and the process of care significantly improved after accreditation.[18] In addition, a retrospective longitudinal study conducted in the United States showed that patients in accredited hospitals had significantly fewer major complication outcomes following laparoscopic bariatric surgery compared to patients in non-accredited hospitals.[19]

Because of the nature of the statistical methods of these studies, whether the statistically significant findings are directly associated with accreditation or if there is a common independent explanatory factor cannot be determined. Some studies assume that the dedication of the top management to a high quality of care could be the primary explanatory factor.[1,20] Although, there is no evidence for this assumption, if there are indeed any kind of independent explanatory factors, then this creates a situation in which it is very difficult to determine whether obtaining accreditation is the true cause of the high quality of care within the institution. One possible way to determine if this is a

relevant question is to compare the activities of hospitals before applying for accreditation to those who have not applied for accreditation. If we identify significant advantages for the hospitals that did apply for accreditation, then the conclusions of previous research studies need to be reinterpreted and future studies are needed to identify the independent factors that explain both the intent for accreditation and the high quality of care.

To understand the circumstances of the current study, the following paragraphs provide an abridged description of the creation of the Hungarian accreditation system for health care. To supplement the ISO 9001 and Hungarian Health Care Standards certifications already used in the Hungarian health care system and to follow the trend of European countries[21] [22] the plan to introduce an accreditation programme was considered in the early 2000s. A decade later, in December 2012, the two-year EU-funded Social Renewal Operating Program (TÁMOP) 6.2.5.A-12/1-2012-0001 project was initiated to create the foundations of a voluntary Hungarian accreditation programme for health care.[23] With a high emphasis on patient safety and following the requirements defined by the International Society for Quality in Healthcare (ISQua), the accreditation standards and the assessment method for inpatient and outpatient institutions and public pharmacies were created by the end of the project.[23] [24] In addition, the accreditation programme obtained its official name: the Accreditation of Healthcare Providers for Safe Patient Care (BELLA).

The next project, TÁMOP-6.2.5/B-13/1-2014-0001, included multiple interventions to improve the quality of Hungarian health care, and one of these interventions was to prepare medical institutions to join the BELLA accreditation programme. This preparatory project lasted from October 2014 to November 2015, and overall, forty-five hospitals and outpatient institutions participated in it.[25] When voluntarily joining the project, the institutions guaranteed that after the project ended, they would apply for the BELLA accreditation; otherwise, they would have to pay back the financial support that was provided by the project. Because of this high level of commitment, we assume that these institutions take the process of being accredited very seriously.

METHODS

Aims of the study

The aims of this study were two-fold: first, to determine if the general hospitals, before joining the nationwide preparatory project for BELLA accreditation, had more mature quality management, patient information and identification, internal professional regulation, surgical procedures, pressure sore prevention and infection control and determine if the heads of quality management at these institutions had a better opinion of the usefulness of quality management and clinical audits compared to the other general hospitals that did not join the project. The second aim was to investigate how the financial status of the hospitals might have influenced the decision to apply for this preparatory project. Since joining this project had financial benefits, we assumed that general hospitals with a worse financial background were more open to join the project.

Data collection and data processing

The questionnaire from the 2013 Hungarian national hospital survey was used in this study and was created by the first two and last two authors of this paper. In the questionnaire, 144 questions involved general information about the institution, quality management, patient information, patient identification, internal professional regulation, safe surgery, pressure sore prevention and infection control. Furthermore, at the end of the questionnaire that considered quality management and internal professional regulation, seven specific questions were asked of the heads of quality management on the usefulness of quality management, and three additional questions were asked on the usefulness of clinical audits. These were the only professional questions that had continuous answer options from 1 to 5, whereas the others had single or multiple-choice options. All questions covered the state of the hospital on the 31st of December 2013.

For the national survey, permission was given by the National Institute of Quality and Organizational Development in Healthcare and Medicines, which supervises and controls the 105 state-owned hospitals. The data collection was conducted online with the EvaSys program (EvaSys Education Survey Automation Suite, Version. 6, Electric Paper Evaluationssysteme GmbH, Lüneburg,

Germany). The data collection was performed in two phases. In the first phase, which lasted from February to June 2014, all 113 hospitals, which were members of the Hungarian Hospital Alliance, were addressed. Because the response rate was too low, the Department of Health Policy of the Hungarian Ministry of Human Capacities was asked to support the survey. After an agreement was made, the second phase of the data collection was performed from October to December 2014. Because of the circular provided by the Department of Health Policy, the response rate nearly doubled, and in the end, 81 hospitals (71.7% response rate) answered the questionnaire.

Because of the heterogeneous characteristics of the hospitals, several exclusion criteria were applied. From the original 81 hospitals in the database, those that are not general hospitals were ignored. Four types of basic inpatient care – inpatient medicine for adults, inpatient medicine for children, surgery and obstetrics – had to be provided in order for a hospital to be considered a general hospital. Of the remaining 46 hospitals, one had participated in the creation of the BELLA accreditation standards. Because it had a head start, we assumed that in this institution, both the quality management and patient care were already influenced by the accreditation standards. In addition, one university hospital provided answers at the departmental level. Although attempts were made to generalize the answers to an institutional level, the answers varied to such a degree that it made a reliable generalization unfeasible. The remaining 44 hospitals had bed numbers higher than 130, which was one of the requirements to participate in the Deepening our Understanding of Quality Improvement in Europe (DUQuE) research project.[26] To check whether the response rate was sufficient for drawing general conclusions at a national level, the National Health Insurance's Annual Report on Hospital Bed Size and Patient Flow for 2013, which contains a list of all the hospitals in Hungary on the 31st of December 2013, was used as a reference point.[27]

The questions considering the quality management and patient care activities were dichotomized, and the answers that were positive were aggregated for each hospital by dimension. The answers concerning the opinion on the usefulness of quality management and clinical audits were treated separately, and, therefore, the first dimension had a possible score between 7 and 35, and the second dimension had a possible score between 3 and 15. Thereafter, the percentage was calculated from the possible maximum score for every dimension. In the survey, each question had the option of

"I cannot/do not want to answer the question," and the hospitals, in many instances, took the opportunity to select this answer. In addition, on rare occasions, some questions remained unanswered. For these reasons, the answering ratio for the questions for each dimension had to be 90% or above. In cases where a hospital answered less than 90% of the questions of a dimension, that dimension was ignored in the statistical calculation for the given hospital.

The financial status of the hospital was measured using the institutions' overall debt in Hungarian currency (HUF). These data were obtained from the Hungarian State Treasury (MÁK) for each general hospital regarding the last month of 2013. To avoid the confounding factor of the hospital size, the hospitals' debt was calculated per the number of beds and per the number of patients discharged in 2013 separately.

The list of hospitals that participated in the nationwide preparatory project for the BELLA accreditation was obtained from the National Healthcare Service Centre (ÁEEK). This list was the basis for arranging the hospitals that answered the previous 2013 surveys into two groups, namely, participating and non-participating hospitals.

Statistical analysis

Cronbach's alpha was used to test the internal reliability of the dimensions of the questionnaire, and the Kolmogorov-Smirnov test was applied to check the normality of the distributions of each dimension for both groups depending on their participation in the project. We rejected the normality if the p value was <0.01. A Spearman correlation was used to investigate the possible associations between the dimensions. To determine the statistical significance of the differences between the two groups, a Mann-Whitney U test and an independent t-test were used depending on the normality of the distributions. With the exception of the test of normality, the level of significance was set at <0.05 for the entire statistical analysis. The SPSS 22 software program (SPSS for Windows, Version 22.0, IBM Inc., Released 2013. Armonk, NY, USA) was used during the statistical analysis.

RESULTS

Descriptive statistics

The 44 general hospitals included in this study represented 73.3% of all general hospitals in Hungary in 2013. Of these hospitals, fourteen joined the preparatory project for the BELLA accreditation, and the answers of the remaining thirty were used for comparison. The hospital-related characteristics of the forty-four institutions are indicated in table 1. Of the four hospitals that completed the questionnaire and were owned by a private company or by a foundation, none were general hospitals. Thus, only public hospitals were analysed in this study.

Table 1 Characteristics of the general hospitals that participated in the study

Characteristics	Participated in the preparatory project[1] (N=14)		Did not participate in the preparatory project[1] (N=30)		Total (N=44)	
Ownership						
EMMI[2]	1	7.1%	2	6.7%	3	6.8%
GYEMSZI[3]	12	85.7%	26	86.7%	38	86.4%
Other ministry	1	7.1%	2	6.7%	3	6.8%
Private	0	0%	0	0%	0	0%
Teaching status						
University hospital	1	7.1%	2	6.7%	3	6.8%
Teaching hospital	9	64.3%	22	73.3%	31	70.5%
Non-teaching hospital	4	28.6%	6	20.0%	10	22.7%
Hospital beds						
131-500	4	28.6%	12	40.0%	16	36.4%
501-1000	2	14.3%	10	33.3%	12	27.3%
>1000	8	57.1%	8	26.7%	16	36.4%
Certification / excellence award						
ISO 9001:2008	12	85.7%	29	96.7%	41	93.2%
ISO 14001:2005	8	57.1%	10	33.3%	18	40.9%
OHSAS 18001:2007	2	14.3%	1	3.3%	3	6.8%
HHCS[4]	11	78.6%	18	60.0%	29	65.9%
EFQM	2	14.3%	1	3.3%	3	6.8%

[1] The preparatory project for the BELLA accreditation.
[2] EMMI: Ministry of Human Capacities
[3] GYEMSZI: Directorate General of IT and Health System Analysis
[4] HHCS: Hungarian Health Care Standards

Answering ratio of questions, normality and internal reliability

When the answering ratios of questions for each dimension were assessed, overall, thirty-four answers were excluded at a dimensional level (table 2). The test of normality varied according to dimension and participation. The internal reliability was strong in quality management (p=0.78) and pressure sore prevention (p=0.80), as well as in the opinion on quality management (p=0.89) and clinical audits (p=0.86). There was a somewhat below acceptance level of internal reliability in safe surgery (p=0.64), and the internal reliability was weak in patient information and identification (p=0.35), internal professional regulation (p=0.49) and infection control (p=0.57).

Table 2 Answering ratio of questions, normality and internal reliability of the dimensions

Dimension (N=number of questions)	Participated in the preparatory project[1]			Did not participate in the preparatory project[1]			Cronbach's alpha (p value)[2]
	Answer below 90% (N)	Answer 90% or above (N)	Kolmogorov-Smirnov test (p value)[2]	Answer below 90% (N)	Answer 90% or above (N)	Kolmogorov-Smirnov test (p value)[2]	
Quality management (N=19)	1	13	0.001	3	27	0.003	0.78
Patient information and identification (N=10)	0	14	<0.001	1	29	<0.001	0.35
Internal professional regulation (N=10)	2	12	0.20	0	30	0.014	0.49
Safe surgery (N=35)	3	11	0.14	2	28	0.04	0.64
Pressure sore prevention (N=34)	0	14	0.20	0	30	0.20	0.80
Infection control (N=18)	0	14	0.10	3	27	0.025	0.57
Opinion on quality management (N=7)	0	14	0.20	4	26	0.20	0.89
Opinion on clinical audit (N=3)	0	14	0.043	6	24	<0.001	0.86

[1] *The preparatory project for the BELLA accreditation.*
[2] *Calculations were only made where the answering ratio for the questions was 90% or greater.*

Table 3 Spearman's correlation matrix of the dimensions

Dimensions (N=number of questions)	QM[1]		PII[2]		IPR[3]		SS[4]		PSP[5]		IC[6]		OQM[7]	
	r value	p value	r value	p value	r value	p value	r value	p value	r value	p value	r value	p value	r value	p value
Quality management (N=19)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Patient information / identification (N=10)	0.29	0.07	-	-	-	-	-	-	-	-	-	-	-	-
Internal professional regulation (N=10)	0.52	0.001*	0.20	0.20	-	-	-	-	-	-	-	-	-	-
Safe surgery (N=35)	0.31	0.07	0.10	0.53	0.16	0.34	-	-	-	-	-	-	-	-
Pressure sore prevention (N=34)	0.02	0.92	0.13	0.42	0.27	0.08	0.06	0.73	-	-	-	-	-	-
Infection control (N=18)	0.06	0.71	-0.11	0.16	0.16	0.33	0.09	0.60	0.48	0.001*	-	-	-	-
Opinion on quality management (N=7)	0.03	0.85	0.23	0.15	0.26	0.12	0.31	0.07	0.15	0.34	0.13	0.45	-	-
Opinion on clinical audits (N=3)	-0.03	0.99	-0.17	0.32	0.39	0.019*	0.34	0.050	0.27	0.10	0.09	0.62	0.60	<0.001*

[1]Quality management, [2]patient information and identification, [3]internal professional regulation, [4]safe surgery, [5]pressure sore prevention, [6]infection control, [7]opinion on quality management, [8]opinion on clinical audits

*p<0.05

Correlation matrix

Spearman's correlation matrix (table 3) reveals significant moderate-level associations between the dimensions of quality management and internal professional regulation (r=0.52, p=0.001), infection control and pressure sore prevention (r=0.48, p=0.001), internal professional regulation and opinion on clinical audits (r=0.39, p=0.019), and opinion on quality management and opinion on clinical audits (r=0.60, p<0.001). Since no strong correlation was identified, a common explanatory factor underlying the dimensions can be ruled out, and thus, these dimensions could be assessed independently from each other.

Table 4 Statistical analysis of the hospitals in each dimension grouped by participation in the project

Dimension (N=number of questions)	Participated in the preparatory project[1]			Did not participate in the preparatory project[1]			Participated vs. did not participate	
	Answer (N)	Mean / median[2]	SD / IQR[2]	Answer (N)	Mean / median[2]	SD / IQR[2]	Statistical method[2]	p value
Quality management (N=19)	13	94.7	13.6	27	89.5	10.5	Mann-Whitney U test	0.669
Patient information and identification (N=10)	14	100.0	10.0	29	100.0	10.0	Mann-Whitney U test	0.963
Internal professional regulation (N=10)	12	86.6	11.5	30	81.8	13.3	Student's t-test	0.280
Safe surgery (N=35)	11	87.9	8.6	28	91.2	5.7	Student's t-test	0.170
Pressure sore prevention (N=34)	14	74.9	12.7	30	72.4	14.7	Student's t-test	0.588
Infection control (N=18)	14	86.7	9.7	27	80.6	11.1	Student's t-test	0.089
Opinion on quality management (N=7)	14	84.7	13.6	26	83.5	13.5	Student's t-test	0.794
Opinion on clinical audit (N=3)	14	83.3	20.0	24	83.3	20.0	Mann-Whitney U test	0.643

[1] The preparatory project for the BELLA accreditation.
[2] Depending on the normality of the distributions.

Comparative statistics

Comparisons of the participating general hospitals with the non-participating hospitals revealed no statistically significant differences in any of the measured activities (table 4). However, it is worth mentioning that in quality management, internal professional regulation and infection control, the difference was greater than 5%, which in all cases favoured the participants of the project. Additionally, the hospitals that participated in the preparatory project had lower means of debt per bed number and per the number of discharged patients than those that did not join, but the differences were not statistically significant (table 5).

Table 5 Statistical analysis of hospital debt grouped by participation

Hospital debt	Participated in the preparatory project[1]			Did not participate in the preparatory project[1]			Participated vs. did not participate	
	K-S test[2] (p value)	Mean	SD	K-S test[2] (p value)	Mean	SD	Statistical method	p value
Total debt of the hospital/ the number of beds (1000 HUF)	0.162	701.5	392.5	0.181	862.9	654.4	Student's t-test	0.400
Total debt of the hospital/ annual number of patients discharged (1000 HUF)	0.200	19.9	10.3	0.038	23.2	16.1	Student's t-test	0.487

[1] The preparatory project for the BELLA accreditation.
[2] Kolmogorov-Smirnov test.

DISCUSSION

Implications for the BELLA accreditation

Because earlier studies had shown that neither ISO 9001, the Hungarian Hospital Care Standards nor the Hungarian Health Care Standards (HHCS) had provided substantial benefits for hospitals regarding health-specific activities[28 29] it is imperative that we assess in what areas the BELLA accreditation will give added value to the hospitals in Hungary. To date, only one published study has

addressed this question.[30] Although this research only investigated the changes in patient safety culture among staff members before and after the development of the BELLA accreditation standards, these results might indicate the actual benefits after the hospitals obtain their accreditation. According to the findings, a statistically significant improvement was detected regarding organizational learning, continuous improvement, communication openness and teamwork.

Our study gives context for future studies investigating the impact of the BELLA accreditation. Since no significant advantages were detected among the hospitals applying for the preparatory project, future differences can be solely contributed to the accreditation. Furthermore, the notion that the hospitals only joined the EU-funded project for financial gains is questioned by the finding that the average debt rate of these hospitals was lower than those that did not join the project.

Implications for international studies

Surprisingly, no connection was found between quality management activities and the opinions on their usefulness (r=0.03, p=0.85). In addition, although most of the heads of quality management agreed with the usefulness of clinical audits, only 24.4% of the general hospitals reported conducting at least one in 2013.[31] Furthermore, in many cases, nursing audits and process audits were reported as clinical audits; thus, the ratio of hospitals that use genuine clinical audits in Hungary is much smaller. All of these results might lead to the conclusion that the usefulness of asking the opinions of the heads of quality management on various activities is questionable. A possible explanation is that the opinions of the heads of quality management are a reflection of what should be, not of reality. For example, the heads of quality management may understand the importance of clinical audits, but without sufficient support from top management, they cannot be properly implemented. This assumption should be investigated in future studies.

The results of the comparative statistics suggest that the assumption that there might be an independent explanatory factor explaining both the intent for accreditation and high quality of care [1 20] is unfounded. Thus, the benefits identified in quantitative studies regarding hospitals are indeed due to being accredited.

The reasons why hospitals apply for accreditation require further investigation. According to our results, the maturity of quality management, patient care and the financial status of a hospital do not significantly influence such decisions. This statement is most likely true for hospital characteristics in general. In countries where accreditation is not mandatory, the management has the authority to initiate the process to apply for one. Therefore, it would be worthwhile to investigate the various attitudes and beliefs of management and to identify the key factors that make them more open to obtaining an accreditation for their hospitals.

Strengths and limitations

Because of the 73.3% response rate, the findings of this study can be generalized to all public general hospitals in Hungary. Additionally, because the survey was conducted in a single country, including confounding factors, such as different health policies or financial environments, in the analysis was unnecessary. However, the 2013 questionnaire was originally designed for a national survey, not as a research instrument. The low Cronbach's alpha score in three dimensions of patient care is attributed to this shortcoming. Nevertheless, the dimensions of quality management, pressure sore prevention and the opinions on quality management and clinical audits have strong internal reliability. Additionally, the answer option "I cannot/Do not want to answer the question" acted as a double-edged sword. This option prevented hospitals from giving false information on specific activities because the question was ambiguous or it touched upon a sensitive topic. However, this answer option led to a situation where not all questions were answered in each dimension per hospital, which weakened the overall level of evidence of the conclusions drawn from the statistical analysis. Because using valid information is more important than swelling the number of the sample, we believe that the benefits of introducing this option in the questionnaire outweighed the overall costs.

CONCLUSION

The results of this study indicate that hospital characteristics – such as the maturity of quality management, patient care and the debt rate – do not contribute to or inhibit the chance for applying for

an accreditation programme. To better understand why hospitals apply for an accreditation, a different approach is needed. Perhaps, changes in the regulatory framework, creating better incentives for enhancing the quality of care of the public hospitals or obtaining private insurance contracts attracting more privately financed cases could increase the interest of hospital management in the application for this accreditation.

We suggest that future studies addressing this question should focus on the various knowledge, interests, attitudes and beliefs of the hospital management regarding accreditation and quality in general.

Contributions

VD and SG designed the study, wrote the first draft of the paper and coordinated the contributions from the other co-authors. VD, SG, BM and TG created the questionnaire and conducted the nationwide hospital survey of 2013. JS and OKBCs designed and conducted the statistical analyses. CsD planned and interpreted the analysis regarding hospital debt. All the authors made critical comments on the drafts of the paper. All the authors read and approved the final manuscript.

Competing interests

VD and SG were involved in and supported by the European Union-funded TÁMOP-6.2.5.A-12/1-2012-0001 project, which sought to create the foundation of a Hungarian accreditation system called the Accreditation of Healthcare Providers for Safe Patient Care (BELLA). The other authors declare that they have no competing interests.

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Data available on request from the corresponding author.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 6
Methods			
Study design	4	Present key elements of study design early in the paper	Page 6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 6-8
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Page 7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 7-8
Bias	9	Describe any efforts to address potential sources of bias	Page 7-8
Study size	10	Explain how the study size was arrived at	Page 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 8
		(*b*) Describe any methods used to examine subgroups and interactions	Page 8
		(*c*) Explain how missing data were addressed	Page 8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 7 and page 9
		(b) Give reasons for non-participation at each stage	Page 7
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 9
		(b) Indicate number of participants with missing data for each variable of interest	Page 10-11
Outcome data	15*	Report numbers of outcome events or summary measures	Page 12-13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 12-13
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 10-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 14-15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 15-16
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	NA

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Investigating the association of the intention to join an accreditation programme with the maturity of quality management, patient care and debt among hospitals: a cross-sectional study in Hungary

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Title page

Title: Investigating the association of the intention to join an accreditation programme with the maturity of quality management, patient care and debt among hospitals: a cross-sectional study in Hungary

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ABSTRACT

Objective: Quantitative studies have shown the various benefits for having accreditation in hospitals. However, neither of these explored the general conditions before applying for an accreditation. To close this gap this study aimed to investigate the possible association between joining an accreditation programme with various hospital characteristics.

Design: A cross-sectional study was implemented using the databases of the 2013 Hungarian hospital survey and of the Hungarian State Treasury.

Setting: Public general hospitals in Hungary.

Participants: The analysis involved 44 public general hospitals, fourteen of which joined the preparatory project for a newly developed accreditation programme.

Main outcome measures: The outcomes included the percentage of compliance in quality management, patient information and identification, internal professional regulation, safe surgery, pressure sore prevention, infection control, the opinions of the heads of quality management regarding the usefulness of quality management and clinical audits, and finally, the total debt of the hospital per bed and per discharged patient.

Results: According to our findings, the general hospitals joining the preparatory project of the accreditation programme performed better in four of the six investigated activities, the head of quality management had a better opinion on the usefulness of quality management, and both the debt per bed number and the debt per discharged patient were lower than those who did not join. However, no statistically significant differences between the two groups were found in any of the examined outcomes.

Conclusions: The findings suggest that hospitals applying for an accreditation programme do not differ significantly in characteristics from those which did not apply. This means that if in the future the accredited hospitals become better compared than other hospitals, then the improvement could be solely contributed to the accreditation.

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Strengths and limitations of this study

- Due to the high response rate, the findings of this study can be generalized to all public general hospitals in Hungary.

- Since the hospital survey was conducted in a single country, different health policies or financial environments did not impact the findings.

- The findings cannot be generalized to private hospitals.

- The questionnaire used in the study was originally designed for a national survey, not as a research instrument.

INTRODUCTION

The quantitative studies that investigate the usefulness of accreditation in health care are based on the premise that the written regulations in the accreditation standards directly influence the process of care. From studies that address this topic, we know that the accreditation of hospitals is associated with more mature quality management, better clinical practice,[1] safer patient care,[1][2] increased compliance in documentation,[3-5] shorter length of stay for psychiatric inpatients[6] better attitudes towards medication error reporting,[7] and lower proportion of errors in medical prescriptions[8] but are not associated with better performance measures for acute stroke, heart failure and ulcers.[9] Furthermore, accreditation was shown to stimulate the improvement in health service organisations and promote of high quality organisational processes[10] while also predict organizational culture and leadership.[11] Although accreditation does not affect outcomes directly we assume that if a positive association exists between accreditation and the process of care, then this positive effect must also be reflected in various outcomes. Although none of the studies found any association between accreditation and patient satisfaction,[12-15] Danish studies have revealed that patients in fully accredited hospitals had a lower 30-day mortality risk[16] and a modestly shorter length of stay but not a lower chance of acute readmission compared to patients in partially accredited hospitals,[17] and the process of care significantly improved after accreditation.[18] Also, a recent study had also revealed a positive association between the compliance with accreditation standards and the level of evidence based hospital care.[19] In addition, a retrospective longitudinal study conducted in the United States showed that patients in accredited hospitals had significantly fewer major complication outcomes following laparoscopic bariatric surgery compared to patients in non-accredited hospitals.[20]

Because of the nature of the statistical methods of these studies, whether the statistically significant findings are directly associated with accreditation or if there is a common independent explanatory factor cannot be determined. Some studies assume that the dedication of the top management to a high quality of care could be the primary explanatory factor.[1][21] Although, there is no evidence for this assumption, if there are indeed any kind of independent explanatory factors, then this creates a situation in which it is very difficult to determine whether obtaining accreditation is the true

cause of the high quality of care within the institution. One possible way to determine if this is a relevant question is to compare the activities of hospitals before applying for accreditation to those who have not applied for accreditation. If we identify significant advantages for the hospitals that did apply for accreditation, then the conclusions of previous research studies need to be reinterpreted and future studies are needed to identify the independent factors that explain both the intent for accreditation and the high quality of care.

To understand the circumstances of the current study, the following paragraphs provide an abridged description of the creation of the Hungarian accreditation system for health care. To supplement the ISO 9001 and Hungarian Health Care Standards certifications already used in the Hungarian health care system and to follow the trend of European countries[22][23] the plan to introduce an accreditation programme was considered in the early 2000s. A decade later, in December 2012, the two-year EU-funded Social Renewal Operating Program (TÁMOP) 6.2.5.A-12/1-2012-0001 project was initiated to create the foundations of a voluntary Hungarian accreditation programme for health care.[24] With a high emphasis on patient safety and following the requirements defined by the International Society for Quality in Healthcare (ISQua), the accreditation standards and the assessment method for inpatient and outpatient institutions and public pharmacies were created by the end of the project.[24][25] In addition, the accreditation programme obtained its official name: the Accreditation of Healthcare Providers for Safe Patient Care (BELLA).

The next project, TÁMOP-6.2.5/B-13/1-2014-0001, included multiple interventions to improve the quality of Hungarian health care, and one of these interventions was to prepare medical institutions to join the BELLA accreditation programme. This preparatory project lasted from October 2014 to November 2015, and overall, thirty hospitals and fifteen outpatient institutions participated in it.[26] When voluntarily joining the project, the institutions guaranteed that after the project ended, they would apply for the BELLA accreditation; otherwise, they would have to pay back the financial support that was provided by the project. Because of this high level of commitment, we assume that these institutions take the process of being accredited very seriously.

METHODS

Aims of the study

The aims of this study were two-fold: first, to determine if a difference already existed between the general hospitals, before the decision of joining or not joining the nationwide preparatory project for BELLA accreditation was made. To this end we compared the hospitals in areas such as the maturity of quality management, patient information and identification, internal professional regulation, surgical procedures, pressure sore prevention, infection control as well as the quality managers' opinion of the usefulness of quality management and clinical audits. The second aim was to investigate how the financial status of the hospitals might have influenced the decision to apply for this preparatory project. The investigation of this aim could have gone both ways. Either the hospitals with better financial status were the ones that could afford to apply for the project, or because of the lack of it the hospitals joining were desperate to get the financial benefits that came with the project. As no similar studies have been conducted before, both of the initial assumptions were considered feasible.

Data collection and data processing

The questionnaire from the 2013 Hungarian national hospital survey was used in this study and was created by the first two and last two authors of this paper. The foundation of the questionnaire was the 2009 national survey of the Health Insurance Supervisory Authority which was also used to study the association between the ISO 9001:2008 and the Hungarian Health Care Standards certifications and various quality-related activities.[27] In the revised 2013 questionnaire, 144 questions involved general information about the institution, quality management, patient information, patient identification, internal professional regulation, safe surgery, pressure sore prevention and infection control. The quality management dimension included various activities regarding quality planning, quality control, quality assurance and quality improvement. Patient information and patient identification were in the same dimension in which the former asked when the patient was informed and by whom, while the latter asked if there was a local protocol on how to identify patients and if so, which patient groups are

included in it. The internal professional regulation dimension asked questions regarding reanimation and the usage of local protocols and clinical audit. The question of the safe surgery questions were mostly from the World Health Organization surgical safety checklist,[28] while the pressure sore prevention and infection control dimensions asked questions on how these activities are conducted and in what manner are these documented, respectively.

At the end of the questionnaire that considered quality management and internal professional regulation, seven specific questions were asked of the heads of quality management on the usefulness of quality management, and three additional questions were asked on the usefulness of clinical audits. These were the only professional questions that had continuous answer options from 1 to 5, whereas the others had single or multiple-choice options. All questions covered the state of the hospital on the 31st of December 2013.

For the national survey, permission was given by the National Institute of Quality and Organizational Development in Healthcare and Medicines, which supervises and controls the 105 state-owned hospitals. The data collection was conducted online with the EvaSys program (EvaSys Education Survey Automation Suite, Version. 6, Electric Paper Evaluationssysteme GmbH, Lüneburg, Germany). The data collection was performed in two phases. In the first phase, which lasted from February to June 2014, all 113 hospitals, which were members of the Hungarian Hospital Alliance, were addressed. Because the response rate was too low, the Department of Health Policy of the Hungarian Ministry of Human Capacities was asked to support the survey. After an agreement was made, the second phase of the data collection was performed from October to December 2014. Because of the circular provided by the Department of Health Policy, the response rate nearly doubled, and in the end, 81 hospitals (71.7% response rate) answered the questionnaire.

Because of the heterogeneous characteristics of the hospitals, several exclusion criteria were applied. From the original 81 hospitals in the database, those that are not general hospitals were ignored. Due to the lack of a uniform definition for a general hospital, the decision was made that four types of basic inpatient care – inpatient medicine for adults, inpatient medicine for children, surgery and obstetrics – had to be provided in order for a hospital to be considered a general hospital. Of the remaining 46 hospitals, one had participated in the creation of the BELLA accreditation standards.

Because it had a head start, we assumed that in this institution, both the quality management and patient care were already influenced by the accreditation standards. In addition, one university hospital provided answers at the departmental level. Although attempts were made to generalize the answers to an institutional level, the answers varied to such a degree that it made a reliable generalization unfeasible. The remaining 44 hospitals had bed numbers higher than 130, which was one of the requirements to participate in the Deepening our Understanding of Quality Improvement in Europe (DUQuE) research project.[29] To check whether the response rate was sufficient for drawing general conclusions at a national level, the National Health Insurance's Annual Report on Hospital Bed Size and Patient Flow for 2013, which contains a list of all the hospitals in Hungary on the 31st of December 2013, was used as a reference point.[30]

The questions considering the quality management and patient care activities were dichotomized, and the answers that were positive were aggregated for each hospital by dimension. The answers concerning the opinion on the usefulness of quality management and clinical audits were treated separately, and, therefore, the first dimension had a possible score between 7 and 35, and the second dimension had a possible score between 3 and 15. Thereafter, the percentage was calculated from the possible maximum score for every dimension. In the survey, each question had the option of "I cannot/do not want to answer the question," and the hospitals, in many instances, took the opportunity to select this answer. In addition, on rare occasions, some questions remained unanswered. For these reasons, the answering ratio for the questions for each dimension had to be 90% or above. In cases where a hospital answered less than 90% of the questions of a dimension, that dimension was ignored in the statistical calculation for the given hospital.

The financial status of the hospital was measured using the institutions' overall debt in Hungarian currency (HUF). These data were obtained from the Hungarian State Treasury (MÁK) for each general hospital regarding the last month of 2013. To avoid the confounding factor of the hospital size, the hospitals' debt was calculated per the number of beds and per the number of patients discharged in 2013 separately.

The list of hospitals that participated in the nationwide preparatory project for the BELLA accreditation was obtained from the National Healthcare Service Centre (ÁEEK). This list was the

basis for arranging the hospitals that answered the previous 2013 surveys into two groups, namely, participating and non-participating hospitals.

Statistical analysis

Cronbach's alpha was used to test the internal reliability of the dimensions of the questionnaire, and the Kolmogorov-Smirnov test was applied to check the normality of the distributions of each dimension for both groups depending on their participation in the project. We rejected the normality if the p value was <0.01. A Spearman correlation was used to investigate the possible associations between the dimensions. To determine the statistical significance of the differences between the two groups, a Mann-Whitney U test and an independent t-test were used depending on the normality of the distributions. With the exception of the test of normality, the level of significance was set at <0.05 for the entire statistical analysis. The SPSS 22 software program (SPSS for Windows, Version 22.0, IBM Inc., Released 2013. Armonk, NY, USA) was used during the statistical analysis.

RESULTS

Descriptive statistics

The 44 general hospitals included in this study represented 73.3% of all general hospitals in Hungary in 2013. Of the original thirty hospitals that joined the preparatory project for the BELLA accreditation, eleven were not general hospitals and of the remaining nineteen only fourteen took part in the survey. The answers of the thirty hospitals that did not take part in the preparatory project were used for comparison. The hospital-related characteristics of the forty-four institutions are indicated in table 1. Of the four hospitals that completed the questionnaire and were owned by a private company or by a foundation, none were general hospitals. Thus, only public hospitals were analysed in this study.

Table 1 Characteristics of the general hospitals that participated in the study

Characteristics	Participated in the preparatory project[1] (N=14)		Did not participate in the preparatory project[1] (N=30)		Total (N=44)	
Ownership						
EMMI[2]	1	7.1%	2	6.7%	3	6.8%
GYEMSZI[3]	12	85.7%	26	86.7%	38	86.4%
Other ministry	1	7.1%	2	6.7%	3	6.8%
Private	0	0%	0	0%	0	0%
Teaching status						
University hospital	1	7.1%	2	6.7%	3	6.8%
Teaching hospital	9	64.3%	22	73.3%	31	70.5%
Non-teaching hospital	4	28.6%	6	20.0%	10	22.7%
Hospital beds						
131-500	4	28.6%	12	40.0%	16	36.4%
501-1000	2	14.3%	10	33.3%	12	27.3%
>1000	8	57.1%	8	26.7%	16	36.4%
Certification / excellence award						
ISO 9001:2008	12	85.7%	29	96.7%	41	93.2%
ISO 14001:2005	8	57.1%	10	33.3%	18	40.9%
OHSAS 18001:2007	2	14.3%	1	3.3%	3	6.8%
HHCS[4]	11	78.6%	18	60.0%	29	65.9%
EFQM	2	14.3%	1	3.3%	3	6.8%

[1] *The preparatory project for the BELLA accreditation.*
[2] *EMMI: Ministry of Human Capacities*
[3] *GYEMSZI: Directorate General of IT and Health System Analysis*
[4] *HHCS: Hungarian Health Care Standards*

Answering ratio of questions, normality and internal reliability

When the answering ratios of questions for each dimension were assessed, overall, thirty-four answers were excluded at a dimensional level (table 2). The test of normality varied according to dimension and participation. The internal reliability was strong in quality management (α=0.78) and pressure sore prevention (α=0.80), as well as in the opinion on quality management (α=0.89) and clinical audits (α=0.86). There was a somewhat below acceptance level of internal reliability in safe surgery (α=0.64), and the internal reliability was weak in patient information and identification (α=0.35), internal professional regulation (α=0.49) and infection control (α=0.57).

Table 2 Answering ratio of questions, normality and internal reliability of the dimensions

Dimension (N=number of questions)	Participated in the preparatory project[1]			Did not participate in the preparatory project[1]			Cronbach's alpha[2]
	Answer below 90% (N)	Answer 90% or above (N)	Kolmogorov-Smirnov test (p value)[2]	Answer below 90% (N)	Answer 90% or above (N)	Kolmogorov-Smirnov test (p value)[2]	
Quality management (N=19)	1	13	0.001	3	27	0.003	0.78
Patient information and identification (N=10)	0	14	<0.001	1	29	<0.001	0.35
Internal professional regulation (N=10)	2	12	0.20	0	30	0.014	0.49
Safe surgery (N=35)	3	11	0.14	2	28	0.04	0.64
Pressure sore prevention (N=34)	0	14	0.20	0	30	0.20	0.80
Infection control (N=18)	0	14	0.10	3	27	0.025	0.57
Opinion on quality management (N=7)	0	14	0.20	4	26	0.20	0.89
Opinion on clinical audit (N=3)	0	14	0.043	6	24	<0.001	0.86

[1] *The preparatory project for the BELLA accreditation.*
[2] *Calculations were only made where the answering ratio for the questions was 90% or greater.*

Table 3 Spearman's correlation matrix of the dimensions

Dimensions (N=number of questions)	QM[1] r value	QM[1] p value	PII[2] r value	PII[2] p value	IPR[3] r value	IPR[3] p value	SS[4] r value	SS[4] p value	PSP[5] r value	PSP[5] p value	IC[6] r value	IC[6] p value	OQM[7] r value	OQM[7] p value
Quality management (N=19)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Patient information / identification (N=10)	0.29	0.07	-	-	-	-	-	-	-	-	-	-	-	-
Internal professional regulation (N=10)	0.52	0.001*	0.20	0.20	-	-	-	-	-	-	-	-	-	-
Safe surgery (N=35)	0.31	0.07	0.10	0.53	0.16	0.34	-	-	-	-	-	-	-	-
Pressure sore prevention (N=34)	0.02	0.92	0.13	0.42	0.27	0.08	0.06	0.73	-	-	-	-	-	-
Infection control (N=18)	0.06	0.71	-0.11	0.16	0.16	0.33	0.09	0.60	0.48	0.001*	-	-	-	-
Opinion on quality management (N=7)	0.03	0.85	0.23	0.15	0.26	0.12	0.31	0.07	0.15	0.34	0.13	0.45	-	-
Opinion on clinical audits (N=3)	-0.03	0.99	-0.17	0.32	0.39	0.019*	0.34	0.050	0.27	0.10	0.09	0.62	0.60	<0.001*

[1]Quality management, [2]patient information and identification, [3]internal professional regulation, [4]safe surgery, [5]pressure sore prevention, [6]infection control, [7]opinion on quality management, [8]opinion on clinical audits

*p<0.05

Table 4 Statistical analysis of the hospitals in each dimension grouped by participation in the project

Dimension (N=number of questions)	Participated in the preparatory project[1]					Did not participate in the preparatory project[1]					Participated vs Did not participate	
	Answer (N)	Max / Min	Mean / median[2]	Q3 / Q1	SD / IQR[2]	Answer (N)	Max / Min	Mean / median[2]	Q3 / Q1	SD / IQR[2]	Statistical method[2]	p value
Quality management (N=19)	13	100.0 / 36.8	94.7	97.4 / 83.8	13.6	27	100.0 / 47.4	89.5	94.7 / 84.2	10.5	Mann-Whitney U test	0.574
Patient information and identification (N=10)	14	100.0 / 80.0	100.0	100.0 / 90.0	10.0	29	100.0 / 70.0	100.0	100.0 / 90.0	10.0	Mann-Whitney U test	0.706
Internal professional regulation (N=10)	12	100.0 / 60.0	86.6	97.5 / 80.0	11.5	30	100.0 / 50.0	81.8	90.0 / 70.0	13.3	Student's t-test	0.280
Safe surgery (N=35)	11	97.1 / 68.6	87.9	94.3 / 82.9	8.6	28	100.0 / 80.0	91.2	96.4 / 85.7	5.7	Student's t-test	0.170
Pressure sore prevention (N=34)	14	100.0 / 55.9	74.9	83.0 / 63.9	12.7	30	94.1 / 35.3	72.4	82.0 / 61.5	14.7	Student's t-test	0.588
Infection control (N=18)	14	100.0 / 72.2	86.7	100.0 / 77.8	9.7	27	100.0 / 61.1	80.6	88.9 / 72.2	11.1	Student's t-test	0.089
Opinion on quality management (N=7)	14	100.0 / 57.1	84.7	97.1 / 73.6	13.6	26	100.0 / 57.1	83.5	95.0 / 74.3	13.5	Student's t-test	0.794
Opinion on clinical audit (N=3)	14	100.0 / 60.0	83.3	100.0 / 80.0	20.0	24	100.0 / 73.3	83.3	100.0 / 80.0	20.0	Mann-Whitney U test	0.392

[1] *The preparatory project for the BELLA accreditation.*
[2] *Depending on the normality of the distributions.*

Correlation matrix

Spearman's correlation matrix (table 3) reveals significant moderate-level associations between the dimensions of quality management and internal professional regulation (r=0.52, p=0.001), infection control and pressure sore prevention (r=0.48, p=0.001), internal professional regulation and opinion on clinical audits (r=0.39, p=0.019), and opinion on quality management and opinion on clinical audits (r=0.60, p<0.001). Since no strong correlation was identified, a common explanatory factor underlying the dimensions can be ruled out, and thus, these dimensions could be assessed independently from each other.

Table 5 Statistical analysis of hospital debt grouped by participation

Hospital debt	Participated in the preparatory project[1]			Did not participate in the preparatory project[1]			Participated vs did not participate
	Descriptive statistics		K-S test[2] (p value)	Descriptive statistics		K-S test[2] (p value)	Student's t-test (p value)
Total debt of the hospital / the number of beds (1000 HUF)	Max	1543.0		Max	2680.1		
	Min	2.0		Min	0		
	Q3	852.1		Q3	1130.3		
	Q1	439.9	0.162	Q1	317.4	0.181	0.400
	Mean	701.5		Mean	862.9		
	Median	641.7		Median	812.3		
	SD	392.5		SD	654.4		
Total debt of the hospital / annual patients discharged (1000 HUF)	Max	44.0		Max	60.9		
	Min	0.1		Min	0		
	Q3	25.1		Q3	34.1		
	Q1	12.3	0.200	Q1	9.0	0.038	0.487
	Mean	19.9		Mean	23.2		
	Median	20.6		Median	21.4		
	SD	10.3		SD	16.1		

[1] The preparatory project for the BELLA accreditation.
[2] Kolmogorov-Smirnov test.

Comparative statistics

Comparisons of the participating general hospitals with the non-participating hospitals revealed no statistically significant differences in any of the measured activities (table 4). Additionally, the hospitals that participated in the preparatory project had lower means of debt per bed number and per the number of discharged patients than those that did not join, but the differences were not statistically significant (table 5). However, it is worth mentioning that the standard deviations of the debt ratios

were very high. When, attempts were made to remove the outlier data from the calculations, this has not decreased the standard deviations in a meaningful way.

DISCUSSION

Implications for the BELLA accreditation

Because earlier studies had shown that neither ISO 9001, the Hungarian Hospital Care Standards nor the Hungarian Health Care Standards (HHCS) had provided substantial benefits for hospitals regarding health-specific activities[27][31] it is imperative that we assess in what areas the BELLA accreditation will give added value to the hospitals in Hungary. To date, only one published study has addressed this question.[32] Although this research only investigated the changes in patient safety culture among staff members before and after the development of the BELLA accreditation standards, these results might indicate the actual benefits after the hospitals obtain their accreditation. According to the findings, a statistically significant improvement was detected regarding organizational learning, continuous improvement, communication openness and teamwork.

Our study gives context for future studies investigating the impact of the BELLA accreditation. Since no significant advantages were detected among the hospitals applying for the preparatory project, future differences can be solely contributed to the accreditation. Furthermore, the notion that the hospitals only joined the EU-funded project for financial gains is questioned by the finding that the average debt rate of these hospitals was lower than those that did not join the project.

Implications for international studies

Surprisingly, no connection was found between quality management activities and the opinions on their usefulness (r=0.03, p=0.85). In addition, although most of the heads of quality management agreed with the usefulness of clinical audits, only 24.4% of the general hospitals reported conducting at least one in 2013.[33] Furthermore, in many cases, nursing audits and process audits were reported as clinical audits; thus, the ratio of hospitals that use genuine clinical audits in Hungary is much smaller. All of these results might lead to the conclusion that the usefulness of asking the opinions of the heads

of quality management on various activities is questionable. A possible explanation is that the opinions of the heads of quality management are a reflection of what should be, not of reality. For example, the heads of quality management may understand the importance of clinical audits, but without sufficient support from top management, they cannot be properly implemented. This assumption should be investigated in future studies.

The results of the comparative statistics suggest that the assumption that there might be an independent explanatory factor explaining both the intent for accreditation and high quality of care [1] [21] is unfounded. Because no significant differences were identified between the two groups of Hungarian general hospitals, we conclude that accreditation is not a method that selects hospitals which already perform better, but rather it is a tool that – if implemented correctly – can contribute to the further development of hospital activities. This also means that the benefits identified in quantitative studies regarding hospitals are indeed due to the accreditation.

Our study did not explore how the top management differ in hospitals that applied for an accreditation programme from those that did not. Since in countries where accreditation is not mandatory, the management has the authority to initiate the process to apply for one, it would be worthwhile to investigate the various attitudes and beliefs of management and to identify the key factors that make them more open to obtaining an accreditation for their hospitals.

Strengths and limitations

Because of the 73.3% response rate, the findings of this study can be generalized to all public general hospitals in Hungary. Alas, the sample size was not high enough to manage the high standard deviations of the debt ratios. Because the survey was conducted in a single country, including confounding factors, such as different health policies or financial environments, in the analysis was unnecessary. However, no private hospital participated in this study. This due to the fact that there are not many private hospitals in Hungary, they normally provide specialized care and they rarely take part in government or academic surveys. Also, the 2013 questionnaire was originally designed for a national survey, not as a research instrument. The low Cronbach's alpha score in three dimensions of patient care is attributed to this shortcoming. Nevertheless, the dimensions of quality management,

pressure sore prevention and the opinions on quality management and clinical audits have strong internal reliability. Additionally, the answer option "I cannot/Do not want to answer the question" acted as a double-edged sword. This option prevented hospitals from giving false information on specific activities because the question was ambiguous or it touched upon a sensitive topic. However, this answer option led to a situation where not all questions were answered in each dimension per hospital, which weakened the overall level of evidence of the conclusions drawn from the statistical analysis. Because using valid information is more important than swelling the number of the sample, we believe that the benefits of introducing this option in the questionnaire outweighed the overall costs.

CONCLUSION

This is the first study that examines the hospital characteristics before applying for an accreditation programme through statistical methods. That resulted in two key findings. First, since no differences were identified in the maturity of quality management, patient care and the debt rate, both notions that either only hospitals with excellent performance or only hospitals lagging behind the rest are prompted to apply for accreditation are questionable. From this statement rises the second conclusion, that future differences in favour of accredited hospitals could be attributed to the effect of accreditation itself. Both of these conclusions give us a better understanding on the interpretation of results regarding research studies about accreditation in hospital care.

Finally, we suggest that future studies investigating the status of hospitals before applying for an accreditation should focus on the various knowledge, interests, attitudes and beliefs of the hospital management regarding accreditation and quality in general via interviews or questionnaires.

Contributions

VD and SG designed the study, wrote the first draft of the paper and coordinated the contributions from the other co-authors. VD, SG, BM and TG created the questionnaire and conducted the nationwide hospital survey of 2013. JS and OKBCs designed and conducted the statistical analyses. CsD planned and interpreted the analysis regarding hospital debt. All the authors made critical comments on the drafts of the paper. All the authors read and approved the final manuscript.

Competing interests

VD and SG were involved in and supported by the European Union-funded TÁMOP-6.2.5.A-12/1-2012-0001 project, which sought to create the foundation of a Hungarian accreditation system called the Accreditation of Healthcare Providers for Safe Patient Care (BELLA). The other authors declare that they have no competing interests.

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Data sharing statement

Data available on request from the corresponding author.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 6
Methods			
Study design	4	Present key elements of study design early in the paper	Page 6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 6-9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Page 7-9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 8
Bias	9	Describe any efforts to address potential sources of bias	Page 7-8
Study size	10	Explain how the study size was arrived at	Page 7-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 9
		(*b*) Describe any methods used to examine subgroups and interactions	Page 8-9
		(*c*) Explain how missing data were addressed	Page 8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 7,8 and 10
		(b) Give reasons for non-participation at each stage	Page 7-8
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 9-10
		(b) Indicate number of participants with missing data for each variable of interest	Page 10-11
Outcome data	15*	Report numbers of outcome events or summary measures	Page 13-14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 13-14
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 11-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 17
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Investigation of the conditions affecting the joining of Hungarian hospitals to an accreditation programme: a cross-sectional study

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Title page

Title: Investigation of the conditions affecting the joining of Hungarian hospitals to an accreditation programme: a cross-sectional study

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ABSTRACT

Objective: Quantitative studies have shown the various benefits for having accreditation in hospitals. However, neither of these explored the general conditions before applying for an accreditation. To close this gap this study aimed to investigate the possible association between joining an accreditation programme with various hospital characteristics.

Design: A cross-sectional study was implemented using the databases of the 2013 Hungarian hospital survey and of the Hungarian State Treasury.

Setting: Public general hospitals in Hungary.

Participants: The analysis involved 44 public general hospitals, fourteen of which joined the preparatory project for a newly developed accreditation programme.

Main outcome measures: The outcomes included the percentage of compliance in quality management, patient information and identification, internal professional regulation, safe surgery, pressure sore prevention, infection control, the opinions of the heads of quality management regarding the usefulness of quality management and clinical audits, and finally, the total debt of the hospital per bed and per discharged patient.

Results: According to our findings, the general hospitals joining the preparatory project of the accreditation programme performed better in four of the six investigated activities, the head of quality management had a better opinion on the usefulness of quality management, and both the debt per bed number and the debt per discharged patient were lower than those who did not join. However, no statistically significant differences between the two groups were found in any of the examined outcomes.

Conclusions: The findings suggest that hospitals applying for an accreditation programme do not differ significantly in characteristics from those which did not apply. This means that if in the future the accredited hospitals become better compared than other hospitals, then the improvement could be solely contributed to the accreditation.

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Strengths and limitations of this study

- Due to the high response rate, the findings of this study can be generalized to all public general hospitals in Hungary.

- Since the hospital survey was conducted in a single country, different health policies or financial environments did not impact the findings.

- The findings cannot be generalized to private hospitals.

- The questionnaire used in the study was originally designed for a national survey, not as a research instrument.

INTRODUCTION

The quantitative studies that investigate the usefulness of accreditation in health care are based on the premise that the written regulations in the accreditation standards directly influence the process of care. From studies that address this topic, we know that the accreditation of hospitals is associated with more mature quality management, better clinical practice,[1] safer patient care,[1 2] increased compliance in documentation,[3-5] shorter length of stay for psychiatric inpatients[6] better attitudes towards medication error reporting,[7] and lower proportion of errors in medical prescriptions[8] but are not associated with better performance measures for acute stroke, heart failure and ulcers.[9] Furthermore, accreditation was shown to stimulate the improvement in health service organisations and promote of high quality organisational processes[10] while also predict organizational culture and leadership.[11] Although accreditation does not affect outcomes directly we assume that if a positive association exists between accreditation and the process of care, then this positive effect must also be reflected in various outcomes. Although none of the studies found any association between accreditation and patient satisfaction,[12-15] Danish studies have revealed that patients in fully accredited hospitals had a lower 30-day mortality risk[16] and a modestly shorter length of stay but not a lower chance of acute readmission compared to patients in partially accredited hospitals,[17] and the process of care significantly improved after accreditation.[18] Also, a recent study had also revealed a positive association between the compliance with accreditation standards and the level of evidence based hospital care.[19] In addition, a retrospective longitudinal study conducted in the United States showed that patients in accredited hospitals had significantly fewer major complication outcomes following laparoscopic bariatric surgery compared to patients in non-accredited hospitals.[20]

Because of the nature of the statistical methods of these studies, whether the statistically significant findings are directly associated with accreditation or if there is a common independent explanatory factor cannot be determined. Some studies assume that the dedication of the top management to a high quality of care could be the primary explanatory factor.[1 21] Although, there is no evidence for this assumption, if there are indeed any kind of independent explanatory factors, then this creates a situation in which it is very difficult to determine whether obtaining accreditation is the true

cause of the high quality of care within the institution. One possible way to determine if this is a relevant question is to compare the activities of hospitals before applying for accreditation to those who have not applied for accreditation. If we identify significant advantages for the hospitals that did apply for accreditation, then the conclusions of previous research studies need to be reinterpreted and future studies are needed to identify the independent factors that explain both the intent for accreditation and the high quality of care.

To understand the circumstances of the current study, the following paragraphs provide an abridged description of the creation of the Hungarian accreditation system for health care. To supplement the ISO 9001 and Hungarian Health Care Standards certifications already used in the Hungarian health care system and to follow the trend of European countries[22 23] the plan to introduce an accreditation programme was considered in the early 2000s. A decade later, in December 2012, the two-year EU-funded Social Renewal Operating Program (TÁMOP) 6.2.5.A-12/1-2012-0001 project was initiated to create the foundations of a voluntary Hungarian accreditation programme for health care.[24] With a high emphasis on patient safety and following the requirements defined by the International Society for Quality in Healthcare (ISQua), the accreditation standards and the assessment method for inpatient and outpatient institutions and public pharmacies were created by the end of the project.[24 25] In addition, the accreditation programme obtained its official name: the Accreditation of Healthcare Providers for Safe Patient Care (BELLA).

The next project, TÁMOP-6.2.5/B-13/1-2014-0001, included multiple interventions to improve the quality of Hungarian health care, and one of these interventions was to prepare medical institutions to join the BELLA accreditation programme. This preparatory project lasted from October 2014 to November 2015, and overall, thirty hospitals and fifteen outpatient institutions participated in it.[26] When voluntarily joining the project, the institutions guaranteed that after the project ended, they would apply for the BELLA accreditation; otherwise, they would have to pay back the financial support that was provided by the project. Because of this high level of commitment, we assume that these institutions take the process of being accredited very seriously.

METHODS

Aims of the study

The aims of this study were two-fold: first, to determine if a difference already existed between the general hospitals, before the decision of joining or not joining the nationwide preparatory project for BELLA accreditation was made. To this end we compared the hospitals in areas such as the maturity of quality management, patient information and identification, internal professional regulation, surgical procedures, pressure sore prevention, infection control as well as the quality managers' opinion of the usefulness of quality management and clinical audits. The second aim was to investigate how the financial status of the hospitals might have influenced the decision to apply for this preparatory project. The investigation of this aim could have gone both ways. Either the hospitals with better financial status were the ones that could afford to apply for the project, or because of the lack of it the hospitals joining were desperate to get the financial benefits that came with the project. As no similar studies have been conducted before, both of the initial assumptions were considered feasible.

Data collection and data processing

The questionnaire from the 2013 Hungarian national hospital survey was used in this study and was created by the first two and last two authors of this paper. The foundation of the questionnaire was the 2009 national survey of the Health Insurance Supervisory Authority which was also used to study the association between the ISO 9001:2008 and the Hungarian Health Care Standards certifications and various quality-related activities.[27] In the revised 2013 questionnaire, 144 questions involved general information about the institution, quality management, patient information, patient identification, internal professional regulation, safe surgery, pressure sore prevention and infection control. The quality management dimension included various activities regarding quality planning, quality control, quality assurance and quality improvement. Patient information and patient identification were in the same dimension in which the former asked when the patient was informed and by whom, while the latter asked if there was a local protocol on how to identify patients and if so, which patient groups are

included in it. The internal professional regulation dimension asked questions regarding reanimation and the usage of local protocols and clinical audit. The question of the safe surgery questions were mostly from the World Health Organization surgical safety checklist,[28] while the pressure sore prevention and infection control dimensions asked questions on how these activities are conducted and in what manner are these documented, respectively.

At the end of the questionnaire that considered quality management and internal professional regulation, seven specific questions were asked of the heads of quality management on the usefulness of quality management, and three additional questions were asked on the usefulness of clinical audits. These were the only professional questions that had continuous answer options from 1 to 5, whereas the others had single or multiple-choice options. All questions covered the state of the hospital on the 31st of December 2013.

For the national survey, permission was given by the National Institute of Quality and Organizational Development in Healthcare and Medicines, which supervises and controls the 105 state-owned hospitals. The data collection was conducted online with the EvaSys program (EvaSys Education Survey Automation Suite, Version. 6, Electric Paper Evaluationssysteme GmbH, Lüneburg, Germany). The data collection was performed in two phases. In the first phase, which lasted from February to June 2014, all 113 hospitals, which were members of the Hungarian Hospital Alliance, were addressed. Because the response rate was too low, the Department of Health Policy of the Hungarian Ministry of Human Capacities was asked to support the survey. After an agreement was made, the second phase of the data collection was performed from October to December 2014. Because of the circular provided by the Department of Health Policy, the response rate nearly doubled, and in the end, 81 hospitals (71.7% response rate) answered the questionnaire.

Because of the heterogeneous characteristics of the hospitals, several exclusion criteria were applied. From the original 81 hospitals in the database, those that are not general hospitals were ignored. Due to the lack of a uniform definition for a general hospital, the decision was made that four types of basic inpatient care – inpatient medicine for adults, inpatient medicine for children, surgery and obstetrics – had to be provided in order for a hospital to be considered a general hospital. Of the remaining 46 hospitals, one had participated in the creation of the BELLA accreditation standards.

Because it had a head start, we assumed that in this institution, both the quality management and patient care were already influenced by the accreditation standards. In addition, one university hospital provided answers at the departmental level. Although attempts were made to generalize the answers to an institutional level, the answers varied to such a degree that it made a reliable generalization unfeasible. The remaining 44 hospitals had bed numbers higher than 130, which was one of the requirements to participate in the Deepening our Understanding of Quality Improvement in Europe (DUQuE) research project.[29] To check whether the response rate was sufficient for drawing general conclusions at a national level, the National Health Insurance's Annual Report on Hospital Bed Size and Patient Flow for 2013, which contains a list of all the hospitals in Hungary on the 31st of December 2013, was used as a reference point.[30]

The questions considering the quality management and patient care activities were dichotomized, and the answers that were positive were aggregated for each hospital by dimension. The answers concerning the opinion on the usefulness of quality management and clinical audits were treated separately, and, therefore, the first dimension had a possible score between 7 and 35, and the second dimension had a possible score between 3 and 15. Thereafter, the percentage was calculated from the possible maximum score for every dimension. In the survey, each question had the option of "I cannot/do not want to answer the question," and the hospitals, in many instances, took the opportunity to select this answer. In addition, on rare occasions, some questions remained unanswered. For these reasons, the answering ratio for the questions for each dimension had to be 90% or above. In cases where a hospital answered less than 90% of the questions of a dimension, that dimension was ignored in the statistical calculation for the given hospital.

The financial status of the hospital was measured using the institutions' overall debt in Hungarian currency (HUF). These data were obtained from the Hungarian State Treasury (MÁK) for each general hospital regarding the last month of 2013. To avoid the confounding factor of the hospital size, the hospitals' debt was calculated per the number of beds and per the number of patients discharged in 2013 separately.

The list of hospitals that participated in the nationwide preparatory project for the BELLA accreditation was obtained from the National Healthcare Service Centre (ÁEEK). This list was the

basis for arranging the hospitals that answered the previous 2013 surveys into two groups, namely, participating and non-participating hospitals.

Statistical analysis

Cronbach's alpha was used to test the internal reliability of the dimensions of the questionnaire, and the Kolmogorov-Smirnov test was applied to check the normality of the distributions of each dimension for both groups depending on their participation in the project. We rejected the normality if the p value was <0.01. A Spearman correlation was used to investigate the possible associations between the dimensions. To determine the statistical significance of the differences between the two groups, a Mann-Whitney U test and an independent t-test were used depending on the normality of the distributions. With the exception of the test of normality, the level of significance was set at <0.05 for the entire statistical analysis. The SPSS 22 software program (SPSS for Windows, Version 22.0, IBM Inc., Released 2013. Armonk, NY, USA) was used during the statistical analysis.

RESULTS

Descriptive statistics

The 44 general hospitals included in this study represented 73.3% of all general hospitals in Hungary in 2013. Of the original thirty hospitals that joined the preparatory project for the BELLA accreditation, eleven were not general hospitals and of the remaining nineteen only fourteen took part in the survey. The answers of the thirty hospitals that did not take part in the preparatory project were used for comparison. The hospital-related characteristics of the forty-four institutions are indicated in table 1. Of the four hospitals that completed the questionnaire and were owned by a private company or by a foundation, none were general hospitals. Thus, only public hospitals were analysed in this study.

Table 1 Characteristics of the general hospitals that participated in the study

Characteristics	Participated in the preparatory project[1] (N=14)		Did not participate in the preparatory project[1] (N=30)		Total (N=44)	
Ownership						
EMMI[2]	1	7.1%	2	6.7%	3	6.8%
GYEMSZI[3]	12	85.7%	26	86.7%	38	86.4%
Other ministry	1	7.1%	2	6.7%	3	6.8%
Private	0	0%	0	0%	0	0%
Teaching status						
University hospital	1	7.1%	2	6.7%	3	6.8%
Teaching hospital	9	64.3%	22	73.3%	31	70.5%
Non-teaching hospital	4	28.6%	6	20.0%	10	22.7%
Hospital beds						
131-500	4	28.6%	12	40.0%	16	36.4%
501-1000	2	14.3%	10	33.3%	12	27.3%
>1000	8	57.1%	8	26.7%	16	36.4%
Certification / excellence award						
ISO 9001:2008	12	85.7%	29	96.7%	41	93.2%
ISO 14001:2005	8	57.1%	10	33.3%	18	40.9%
OHSAS 18001:2007	2	14.3%	1	3.3%	3	6.8%
HHCS[4]	11	78.6%	18	60.0%	29	65.9%
EFQM	2	14.3%	1	3.3%	3	6.8%

[1] The preparatory project for the BELLA accreditation.
[2] EMMI: Ministry of Human Capacities
[3] GYEMSZI: Directorate General of IT and Health System Analysis
[4] HHCS: Hungarian Health Care Standards

Answering ratio of questions, normality and internal reliability

When the answering ratios of questions for each dimension were assessed, overall, thirty-four answers were excluded at a dimensional level (table 2). The test of normality varied according to dimension and participation. The internal reliability was strong in quality management ($\alpha=0.78$) and pressure sore prevention ($\alpha=0.80$), as well as in the opinion on quality management ($\alpha=0.89$) and clinical audits ($\alpha=0.86$). There was a somewhat below acceptance level of internal reliability in safe surgery ($\alpha=0.64$), and the internal reliability was weak in patient information and identification ($\alpha=0.35$), internal professional regulation ($\alpha=0.49$) and infection control ($\alpha=0.57$).

Table 2 Answering ratio of questions, normality and internal reliability of the dimensions

Dimension (N=number of questions)	Participated in the preparatory project[1]			Did not participate in the preparatory project[1]			Cronbach's alpha[2]
	Answer below 90% (N)	Answer 90% or above (N)	Kolmogorov-Smirnov test (p value)[2]	Answer below 90% (N)	Answer 90% or above (N)	Kolmogorov-Smirnov test (p value)[2]	
Quality management (N=19)	1	13	0.001	3	27	0.003	0.78
Patient information and identification (N=10)	0	14	<0.001	1	29	<0.001	0.35
Internal professional regulation (N=10)	2	12	0.20	0	30	0.014	0.49
Safe surgery (N=35)	3	11	0.14	2	28	0.04	0.64
Pressure sore prevention (N=34)	0	14	0.20	0	30	0.20	0.80
Infection control (N=18)	0	14	0.10	3	27	0.025	0.57
Opinion on quality management (N=7)	0	14	0.20	4	26	0.20	0.89
Opinion on clinical audit (N=3)	0	14	0.043	6	24	<0.001	0.86

[1] *The preparatory project for the BELLA accreditation.*
[2] *Calculations were only made where the answering ratio for the questions was 90% or greater.*

Table 3 Spearman's correlation matrix of the dimensions

Dimensions (N=number of questions)	QM[1]		PII[2]		IPR[3]		SS[4]		PSP[5]		IC[6]		OQM[7]	
	r value	p value	r value	p value	r value	p value	r value	p value	r value	p value	r value	p value	r value	p value
Quality management (N=19)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Patient information / identification (N=10)	0.29	0.07	-	-	-	-	-	-	-	-	-	-	-	-
Internal professional regulation (N=10)	0.52	0.001*	0.20	0.20	-	-	-	-	-	-	-	-	-	-
Safe surgery (N=35)	0.31	0.07	0.10	0.53	0.16	0.34	-	-	-	-	-	-	-	-
Pressure sore prevention (N=34)	0.02	0.92	0.13	0.42	0.27	0.08	0.06	0.73	-	-	-	-	-	-
Infection control (N=18)	0.06	0.71	-0.11	0.16	0.16	0.33	0.09	0.60	0.48	0.001*	-	-	-	-
Opinion on quality management (N=7)	0.03	0.85	0.23	0.15	0.26	0.12	0.31	0.07	0.15	0.34	0.13	0.45	-	-
Opinion on clinical audits (N=3)	-0.03	0.99	-0.17	0.32	0.39	0.019*	0.34	0.050	0.27	0.10	0.09	0.62	0.60	<0.001*

[1]Quality management, [2]patient information and identification, [3]internal professional regulation, [4]safe surgery, [5]pressure sore prevention, [6]infection control, [7]opinion on quality management, [8]opinion on clinical audits

*$p<0.05$

Table 4 Statistical analysis of the hospitals in each dimension grouped by participation in the project

Dimension (N=number of questions)	Participated in the preparatory project[1]					Did not participate in the preparatory project[1]					Participated vs Did not participate	
	Answer (N)	Max / Min	Mean / median[2]	Q3 / Q1	SD / IQR[2]	Answer (N)	Max / Min	Mean / median[2]	Q3 / Q1	SD / IQR[2]	Statistical method[2]	p value
Quality management (N=19)	13	100.0 / 36.8	94.7	97.4 / 83.8	13.6	27	100.0 / 47.4	89.5	94.7 / 84.2	10.5	Mann-Whitney U test	0.574
Patient information and identification (N=10)	14	100.0 / 80.0	100.0	100.0 / 90.0	10.0	29	100.0 / 70.0	100.0	100.0 / 90.0	10.0	Mann-Whitney U test	0.706
Internal professional regulation (N=10)	12	100.0 / 60.0	86.6	97.5 / 80.0	11.5	30	100.0 / 50.0	81.8	90.0 / 70.0	13.3	Student's t-test	0.280
Safe surgery (N=35)	11	97.1 / 68.6	87.9	94.3 / 82.9	8.6	28	100.0 / 80.0	91.2	96.4 / 85.7	5.7	Student's t-test	0.170
Pressure sore prevention (N=34)	14	100.0 / 55.9	74.9	83.0 / 63.9	12.7	30	94.1 / 35.3	72.4	82.0 / 61.5	14.7	Student's t-test	0.588
Infection control (N=18)	14	100.0 / 72.2	86.7	100.0 / 77.8	9.7	27	100.0 / 61.1	80.6	88.9 / 72.2	11.1	Student's t-test	0.089
Opinion on quality management (N=7)	14	100.0 / 57.1	84.7	97.1 / 73.6	13.6	26	100.0 / 57.1	83.5	95.0 / 74.3	13.5	Student's t-test	0.794
Opinion on clinical audit (N=3)	14	100.0 / 60.0	83.3	100.0 / 80.0	20.0	24	100.0 / 73.3	83.3	100.0 / 80.0	20.0	Mann-Whitney U test	0.392

[1] *The preparatory project for the BELLA accreditation.*

[2] *Depending on the normality of the distributions.*

Correlation matrix

Spearman's correlation matrix (table 3) reveals significant moderate-level associations between the dimensions of quality management and internal professional regulation (r=0.52, p=0.001), infection control and pressure sore prevention (r=0.48, p=0.001), internal professional regulation and opinion on clinical audits (r=0.39, p=0.019), and opinion on quality management and opinion on clinical audits (r=0.60, p<0.001). Since no strong correlation was identified, a common explanatory factor underlying the dimensions can be ruled out, and thus, these dimensions could be assessed independently from each other.

Table 5 Statistical analysis of hospital debt grouped by participation

Hospital debt	Participated in the preparatory project[1]			Did not participate in the preparatory project[1]			Participated vs did not participate
	Descriptive statistics		K-S test[2] (p value)	Descriptive statistics		K-S test[2] (p value)	Student's t-test (p value)
Total debt of the hospital / the number of beds (1000 HUF)	Max	1543.0	0.162	Max	2680.1	0.181	0.400
	Min	2.0		Min	0		
	Q3	852.1		Q3	1130.3		
	Q1	439.9		Q1	317.4		
	Mean	701.5		Mean	862.9		
	Median	641.7		Median	812.3		
	SD	392.5		SD	654.4		
Total debt of the hospital / annual patients discharged (1000 HUF)	Max	44.0	0.200	Max	60.9	0.038	0.487
	Min	0.1		Min	0		
	Q3	25.1		Q3	34.1		
	Q1	12.3		Q1	9.0		
	Mean	19.9		Mean	23.2		
	Median	20.6		Median	21.4		
	SD	10.3		SD	16.1		

[1] The preparatory project for the BELLA accreditation.
[2] Kolmogorov-Smirnov test.

Comparative statistics

Comparisons of the participating general hospitals with the non-participating hospitals revealed no statistically significant differences in any of the measured activities (table 4). Additionally, the hospitals that participated in the preparatory project had lower means of debt per bed number and per the number of discharged patients than those that did not join, but the differences were not statistically significant (table 5). However, it is worth mentioning that the standard deviations of the debt ratios

were very high. When, attempts were made to remove the outlier data from the calculations, this has

not decreased the standard deviations in a meaningful way.

DISCUSSION

Implications for the BELLA accreditation

Because earlier studies had shown that neither ISO 9001, the Hungarian Hospital Care Standards nor

the Hungarian Health Care Standards (HHCS) had provided substantial benefits for hospitals

regarding health-specific activities[27] [31] it is imperative that we assess in what areas the BELLA

accreditation will give added value to the hospitals in Hungary. To date, only one published study has

addressed this question.[32] Although this research only investigated the changes in patient safety culture

among staff members before and after the development of the BELLA accreditation standards, these

results might indicate the actual benefits after the hospitals obtain their accreditation. According to the

findings, a statistically significant improvement was detected regarding organizational learning,

continuous improvement, communication openness and teamwork.

Our study gives context for future studies investigating the impact of the BELLA

accreditation. Since no significant advantages were detected among the hospitals applying for the

preparatory project, future differences can be solely contributed to the accreditation. Furthermore, the

notion that the hospitals only joined the EU-funded project for financial gains is questioned by the

finding that the average debt rate of these hospitals was lower than those that did not join the project.

Implications for international studies

Surprisingly, no connection was found between quality management activities and the opinions on

their usefulness ($r=0.03$, $p=0.85$). In addition, although most of the heads of quality management

agreed with the usefulness of clinical audits, only 24.4% of the general hospitals reported conducting

at least one in 2013.[33] Furthermore, in many cases, nursing audits and process audits were reported as

clinical audits; thus, the ratio of hospitals that use genuine clinical audits in Hungary is much smaller.

All of these results might lead to the conclusion that the usefulness of asking the opinions of the heads

of quality management on various activities is questionable. A possible explanation is that the opinions of the heads of quality management are a reflection of what should be, not of reality. For example, the heads of quality management may understand the importance of clinical audits, but without sufficient support from top management, they cannot be properly implemented. This assumption should be investigated in future studies.

The results of the comparative statistics suggest that the assumption that there might be an independent explanatory factor explaining both the intent for accreditation and high quality of care [1] [21] is unfounded. Because no significant differences were identified between the two groups of Hungarian general hospitals, we conclude that accreditation is not a method that selects hospitals which already perform better, but rather it is a tool that – if implemented correctly – can contribute to the further development of hospital activities. This also means that the benefits identified in quantitative studies regarding hospitals are indeed due to the accreditation.

Our study did not explore how the top management differ in hospitals that applied for an accreditation programme from those that did not. Since in countries where accreditation is not mandatory, the management has the authority to initiate the process to apply for one, it would be worthwhile to investigate the various attitudes and beliefs of management and to identify the key factors that make them more open to obtaining an accreditation for their hospitals.

Strengths and limitations

Because of the 73.3% response rate, the findings of this study can be generalized to all public general hospitals in Hungary. Alas, the sample size was not high enough to manage the high standard deviations of the debt ratios. Because the survey was conducted in a single country, including confounding factors, such as different health policies or financial environments, in the analysis was unnecessary. However, no private hospital participated in this study. This due to the fact that there are not many private hospitals in Hungary, they normally provide specialized care and they rarely take part in government or academic surveys. Also, the 2013 questionnaire was originally designed for a national survey, not as a research instrument. The low Cronbach's alpha score in three dimensions of patient care is attributed to this shortcoming. Nevertheless, the dimensions of quality management,

pressure sore prevention and the opinions on quality management and clinical audits have strong internal reliability. Additionally, the answer option "I cannot/Do not want to answer the question" acted as a double-edged sword. This option prevented hospitals from giving false information on specific activities because the question was ambiguous or it touched upon a sensitive topic. However, this answer option led to a situation where not all questions were answered in each dimension per hospital, which weakened the overall level of evidence of the conclusions drawn from the statistical analysis. Because using valid information is more important than swelling the number of the sample, we believe that the benefits of introducing this option in the questionnaire outweighed the overall costs.

CONCLUSION

This is the first study that examines the hospital characteristics before applying for an accreditation programme through statistical methods. That resulted in two key findings. First, since no differences were identified in the maturity of quality management, patient care and the debt rate, both notions that either only hospitals with excellent performance or only hospitals lagging behind the rest are prompted to apply for accreditation are questionable. From this statement rises the second conclusion, that future differences in favour of accredited hospitals could be attributed to the effect of accreditation itself. Both of these conclusions give us a better understanding on the interpretation of results regarding research studies about accreditation in hospital care.

Finally, we suggest that future studies investigating the status of hospitals before applying for an accreditation should focus on the various knowledge, interests, attitudes and beliefs of the hospital management regarding accreditation and quality in general via interviews or questionnaires.

Contributions

VD and SG designed the study, wrote the first draft of the paper and coordinated the contributions from the other co-authors. VD, SG, BM and TG created the questionnaire and conducted the nationwide hospital survey of 2013. JS and OKBCs designed and conducted the statistical analyses. CsD planned and interpreted the analysis regarding hospital debt. All the authors made critical comments on the drafts of the paper. All the authors read and approved the final manuscript.

Competing interests

VD and SG were involved in and supported by the European Union-funded TÁMOP-6.2.5.A-12/1-2012-0001 project, which sought to create the foundation of a Hungarian accreditation system called the Accreditation of Healthcare Providers for Safe Patient Care (BELLA). The other authors declare that they have no competing interests.

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Data sharing statement

Data available on request from the corresponding author.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 6
Methods			
Study design	4	Present key elements of study design early in the paper	Page 6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 6-9
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Page 7-9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 8
Bias	9	Describe any efforts to address potential sources of bias	Page 7-8
Study size	10	Explain how the study size was arrived at	Page 7-8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 9
		(*b*) Describe any methods used to examine subgroups and interactions	Page 8-9
		(*c*) Explain how missing data were addressed	Page 8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	NA
		(*e*) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 7,8 and 10
		(b) Give reasons for non-participation at each stage	Page 7-8
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 9-10
		(b) Indicate number of participants with missing data for each variable of interest	Page 10-11
Outcome data	15*	Report numbers of outcome events or summary measures	Page 13-14
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Page 13-14
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Page 11-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 15-16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 17
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.